Tooth-level versus patient-level

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STATISTICAL CORNER

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MANUSCRIPT

Theoretical scenario

Accidental bracket debondings during fixed appliance treatment can lead to prolonged treatment times and additional costs. It is therefore in the interest of both the orthodontist and the patient that bracket failure rate is kept as low as possible. With that in mind, a group of orthodontists conducted a large-scale multi-centre clinical trial to compare the clinical performance of two adhesives, adhesive A and B (AA and AB, respectively), as described previously (Papageorgiou, 2017). In the previous article the performance of the two theoretical adhesives in terms of bond failure type was described, as measured qualitatively with the Adhesive Remnant Index. The focus of the present article will be on the bracket failure rate of the two adhesives AA and AB.

As far as the trial's methods are concerned, the authors randomised 180 patients from multiple research centres to AA and AB in a parallel fashion: all teeth from right second premolar to left second premolar of both jaws from each patient were bonded with a single adhesive. All first-time failed brackets from each patient up to the completion of fixed appliance treatment were noted by a blinded assessor. The data were analysed initially by descriptive statistics that included absolute and relative (percent) frequencies of bond failure in the two groups. Finally, the authors tested for differences in the failure rate of AA and AB with the chi-square test for equality of two or more proportions from independent samples, considering a two-sided $P < 0.05$ as statistically significant.

A total of 180 patients were randomised in the trial and 20 teeth per patient were bonded and observed during treatment. From the 90 patients (1800 brackets) in each group, 82 and 78 brackets failed in the AA and AB groups. This corresponded to a 4.6% and 4.3% failure rate in the AA and AB group, respectively. The chi-square test yielded a P value of 0.75 and therefore the authors concluded that no differences in the failure rate of AA and AB were found (Table 1).

(*insert Table 1 here*)

Which of the following statements are correct, if any?

A) The outcome of bond failure at the tooth/bracket level (the fate of each bonded bracket) consists of independent observations and therefore the chi-square test was correctly used.

B) The outcome of bond failure at the patient level (if each patient experiences at least one bracket failure) consists of independent observations and therefore the chi-square test can be used.

C) Conclusions drawn from results of the trial at either bracket level or patient level are the same.

D) The results of the trial regarding bond failure can be analysed at either bracket level or patient level without information loss.

The outcome of bond failure at the tooth level does not consist of independent observation, as each of the 3600 brackets bonded on the teeth of the 180 treated patients is not completely independent. On the contrary, the teeth of each set of 20 brackets within each patient's mouth are subject to common conditions and therefore, their fate is to some degree correlated. In other words, observations are clustered within each patient. Clustered data are often found in orthodontics when outcomes at the level of teeth, sextants, quadrants, or jaws are used. Examples of such outcomes with clustered data include bond failure, white spot lesions, gingival recessions, plaque/gingival indexes, or retraction of canines into extraction spaces. Such data might be influenced by several patient-related factors, either known (as patient age, sex, masticatory forces, smoking, oral hygiene, or compliance) or unknown (like genetic predisposition or systemic disease). Most importantly, the statistical analysis of such data needs to take clustering into account by using McNemar's test or more complex methods like logistic regression (for a review of methods see Pandis et al. 2013). So statement (A) is wrong, since the chi-square test is used for independent (non-clustered) samples.

On the other side, the outcome of the number of failed brackets per patient adds up all failed brackets within each patient to a single value and therefore consists of independent observations free of clustering. So we can cross-tabulate the outcome of number of failed brackets per patient with the experimental group (AA or AB) as is done in Table 2 and perform a simple chi-square test for independent samples. Therefore, statement (B) is correct.

Looking at the trial's results using the number of failed brackets per patient (Table 2; Figure 1), we can see that significant differences exist between AA and AB. Patients bonded with AA present a higher bracket success rate (defined as patients with no bracket failure) than patients bonded with AB (56.7% versus 45.6%, respectively). At the same time, every single patient that experienced excessive (3 or 4) bracket failures were bonded with AA, while patients bonded with AB experienced 1 or 2 bracket failures.

There might be many explanations for these results, such as a research centre using a different bonding protocol than the rest or group AA having more male patients, younger patients, or patients with high masticatory loads, as these have been named as factors that might potentially lead to higher bracket failure. Although these findings are open to interpretation, a significant difference was ultimately found between the performance of AA and AB at patient level, but not at tooth level, and therefore statement C is wrong.

(*insert Table 2 and Figure 1 here*)

Furthermore, although using an outcome at the patient level eliminated clustering effects, some information regarding bracket failure might have been lost. It has been suggested for example that bracket failure rates differ between upper and lower teeth or between anterior and posterior teeth (Manning et al. 2006). Such differences are not however reflected on the number of failed brackets per patients, so we have indeed some information loss and statement D is wrong.

We see that a trial's conclusions can vary consistently according to the chosen analysis plan and therefore, both outcome selection and the appropriate analysis have to be planned carefully *a priori* according to the scope of each trial.

References

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TABLES

Table 1. Results of the trial using overall bond failure at the bracket level.

	Adhesive A *Brackets (%)*	**Adhesive B** *Brackets (%)*	**P value (chi-square)**
Brackets - total	1800 (100.0%)	1800 (100.0%)	
Retained brackets	1718 (95.4%)	1722 (95.7%)	0.75
Failed brackets	82 (4.6%)	78 (4.3%)	

Table 2. Results of the trial using overall number of bracket failures at the bracket level.

Failed brackets/ patient	**Adhesive A** *Patients (%)*	**Adhesive B** *Patients (%)*	**P value (chi-square)**
Patients - total	90 (100.0%)	90 (100.0%)	
No failed bracket/ patient	51 (56.7%)	41 (45.6%)	0.001
1 failed bracket/ patient	12 (13.3%)	16 (17.8%)	
2 failed brackets/ patient	16 (17.8%)	33 (36.7%)	
3 failed brackets/ patient	10 (11.1%)	0 (0%)	
4 failed brackets/ patient	1 (1.1%)	0 (0%)	

Figure 1. Bar graph of bracket failure at patient level in terms of number of failed brackets per patient. Results are given in % patients at each bracket failure category for adhesive A (AA; red bars) and adhesive B (AB; blue bars).